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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

: 10/735,601

Confirmation No. 2496

τερρίιcanτ Filed Smith et al.

Filed

December 12, 2003

TC/A.U.

1635

Examiner For Brian A. Whiteman

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MULTI-ANTIGENIC ALPHAVIRUS REPLICON

PARTICLES AND METHODS

Docket No.

95-02

Customer No.:

23713

Commissioner for Patents MAIL STOP AMENDMENT P.O. Box 1450

Alexandria, VA 22313-1450

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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage for Express Mail in an envelope addressed to:

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October 12, 2004

Date

Cathy Nelson

EV 504060670 US Express Mail Tracking Number

INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants respectfully note that additional U. S. patent documents were made of record in an Information Disclosure Statement filed electronically on October 7, 2004.

The Examiner is respectfully requested to consider the references, copies enclosed, which may qualify as prior art. For the Examiner's convenience, the references are listed on the attached Patent and Trademark Office form PTO-1449.

This information is cited in a spirit of forthrightness and cooperation to enable the applicants to obtain that measure of protection for the invention to which there is entitlement. However, no representation is made that the listed art actually qualifies as prior art under the patent statute and the mere use of PTO-1449 is not an admission that all listed references are prior art. No representation is made that applicants know of the best art.

It is believed that this submission does not require the payment of a fee. If this is not correct, please charge any required fee to deposit account no. 07-1969.

Respectfully submitted,

Donna M. Ferber Reg. No. 33,878

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Attorney Docket No. 95-02 October 12, 2004

Substitute for form 1449/PTO, based on P (SB/08A and 08B

INFORMATION DISCLOSURE MADER STATEMENT BY APPLICANT

21	Sheet 1 of 3
Application Number	10/735,601
Filing Date	December 12, 2003
First Named Inventor	Smith et al.
Art Unit	1635
Examiner Name	Brian A. Whiteman
Attorney Docket Number	95-02

GWS 10/12/2004

U.S. PATENT DOCUMENTS

Examiner Initial*	Cite No. ¹	Document Number (US-)	Publication Date (MM-DD-YYYY)	Name .	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear (or entire document unless noted otherwise)

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No. ¹	Foreign Patent Document Number (include WIPO country code)	Publication Date (MM-DD-YYYY)	Name	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear (or entire document unless noted otherwise)	T ²
	1	WO 92/10578	06/25/1992		•	
	2	WO 99/08706	02/25/1999			

NON-PATENT LITERATURE DOCUMENTS

Examiner Initial*	Cite No. ¹	REFERENCE Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	1	Balasuriya et al. (Feb. 2002) "Alphavirus replicon particles expressing the two major envelope proteins of equine arteritis virus induce high level protection against challenge with virulent virus in vaccinated horses"; Vaccine 20:1609-1617.	
	2	Barry et al. (2004) "Expression library immunization to discover and improve vaccine antigens"; <i>Immunological Reviews</i> 199 :68-83	
	3	Bell et al. (Mar. 1978) "Effect of Low-NaCl Medium on the Envelope Glycoproteins of Sindbis Virus"; <i>J. Virol.</i> 25 (3):764-769	
	4	Bergman et al. (Apr. 2003) "Long-Term Survival of Dogs with Advanced Malignant Melanoma after DNA Vaccination with Xenogeneic Human Tyrosinase: A Phase I Trial"; Clin. Cancer Research 9:1284-1290	
	5	Casimiro et al. (Jan. 2002) "Vaccine-induced immune responses in rodents and nonhuman primates by use of a humanized immunodeficiency virus type 1 pol gene"; J. Virol. 76 :185-195	
	6	Frolov et al. (1996) "Alphavirus-based expression vectors: Strategies and applications"; <i>Proc. Natl. Acad. Sci.USA</i> 93 :11371-11377	
	7	Geisbert et al. (May 2002) "Evaluation in Nonhuman Primates of Vaccines against Ebola Virus"; <i>Emerging Infect. Dis.</i> 8 (5):503-507	

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional).
²Applicant is to place a check mark here or "x" if English language Translation is attached.

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INFORMATION DISCLØSURE	9
STATEMENT BY APPLICANT	[9]
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Application Number	10/735,601
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Examiner Name	Brian A. Whiteman
Attorney Docket Number	95-02

GWS 10/12/2004

8	Hahn et al. (1992) "Infectious Sindbis Virus Transient Expression Vectors for Studying	
	Antigen Processing and Presentation," Proc. Natl. Acad. Sci. USA 89:2679-2683	
9	Heiser et al. (Feb. 2002) "Autologous Dendritic Cells Transfected with Prostate-	
.	Specific Antigen RNA Stimulate CTL Responses Against Metastatic Prostate	
	Tumors," J. Clin. Inv. 109(3):409-417	
10	Hevey et al. (1998) "Marburg Virus Vaccines Based upon Alphavirus Replicons	
	Protect Guinea Pigs and Nonhuman Primates"; Virology 251:28-37	L
11	Kinney et al. (1989) The Full-Length Nucleotide Sequences of the Virulent Trinidad	
	Donkey Strain of Venezuelan Equine Encephalitis Virus and Its Attenuated Vaccine	
	Derivative, Strain TC-83," Virology 170:19-30	
12	Koller et al. (Sept. 2001) "A high-throughput alphavirus-based expression cloning	
'-	system for mammalian cells"; Nature Biotech. 19:851-855	
13	Kumamoto et al. (Jan. 2002) "Induction of Tumor-Specific Protective Immunity by in	
'"	situ Langerhans Cell Vaccine," Nature Biotech. 20:64-69	
14	Leitner et al. (Jan.2000) "Enhancement of Tumor-specific Immune Response with	
'4	Plasmid DNA Replicon Vectors"; Cancer Research 60:51-55	
15	Li et al. (October 1996) "Production of infectious recombinant Moloney murine	
13	leukemia virus particles in BHK cells using Semliki Forest virus-derived RNA	
	expression vectors." Proc. Natl. Acad. Sci. USA. 93:11658-11663	-
16	Overwijk et al. (Jan.2001) "Creating therapeutic cancer vaccines: notes from the	
	battlefield"; Trends in Immunol. 22(1):5-7	-
17	Pardoll, D.M. (May 1998) "Cancer Vaccines"; Nature Medicine Vaccine Supplement	
	4(5):525-531	ļ
18	Pardoll, D.M. (Apr. 2002) Spinning Molecular Immunology into Successful	
	Immunotherapy"; Nature Reviews - Immunology 2:227-238	<u> </u>
19	Pushko et al. (1997) "Replicon-Helper systems from Attenuated Venezuelan Equine	*
· '	Encephalitis Virus: Expression of Heterologous Genes in Vitro and Immunization	
	against Heterologous Pathogens in Vivo"; Virology 239:389-401	
20	Ragupathi et al. (Aug. 2002) "The case for polyvalent cancer vaccines that induce	
İ	antibodies"; Expert Rev. Vacciines 1(2):193-206	1
21	Rayner et al. (SepOct. 2002) "Alphavirus Vectors and Vaccination," Rev. Med. Virol.	
	12 :279-296	
22	Sadanaga et al. (Aug. 2001) "Dendritic cell vaccination with MAGE peptide is a novel	
	therapeutic approach for gastrointestinal carcincomas"; Clin. Cancer Res. 7:2277-	
	2284	
23	Slepushkin et al. (SepOct. 2003) "Large scale purification of a lentiviral vector by	<u> </u>
. 20	size exclusion chromatography or mustang Q ion exchange capsule."; <i>Bioprocessing</i>	
	J. p.89-94	İ
24	Waite et al. (Jan. 1970) "Inhibition of Sindbis Virus Production by Media of Low Ionic	\vdash
24	Strength: Intracellular Events and Requirements for Reversal"; <i>J. Virol.</i> 5 :60-71.	
	Ward et al. (Sep. 2002) "Immunotherapeutic Potential of Whole Tumor Cells," Cancer	-
25		
	Immunol. Immunother. 51:351-357.	1

Examiner	Date	
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			SHEELSUIS
Substitute for form 1449/PTO, based on P	TO/SB/08A and 08B	Application Number	10/735,601
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INFORMATION DISCLOS	UREIPE	First Named Inventor	Smith et al.
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	OCT 1 2 2004	Attorney Docket Number	95-02
	F	/	GWS 10/12/2004

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26	Wilson et al. (Aug. 2001) "Vaccine Potential of Ebola Virus VP24, VP30, VP35, and VP40 Proteins"; Virology 286:384-390	
27	Yamanaka et al. (Sept. 2002) Marked enhancement of antitumor immune responses in mouse brain tumor models by genetically modified dendritic cells producing Semliki Forest virus-mediated interleukin-12"; <i>J. Neurosurg.</i> 97 :611-618.	
28	Yamanaka et al. (Mar. 2001) "Enhancement of antitumor immune response in glioma models in mice by genetically modified dendritic cells pulsed with Semliki Forest virus-mediated complementary DNA"; <i>J. Neurosurg.</i> 94 :474-481.	
29	Ying et al. (1999) "Cancer therapy using a self-replicating RNA vaccine"; Nature Medicine 5(7):823-827	•

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